UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,680	01/22/2002	Carl Johan Friddle	LEX-0301-USA	5215

24231 7590 04/15/2005

LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

EXAMINER	
NICHOLS, CHRISTOPHER J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,680	FRIDDLE ET AL.	
	Examiner	Art Unit	
	Christopher J. Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 14 December 2004 has been received and entered in full.

Withdrawn Objections And/Or Rejections

2. The Objection to the Oath/Declaration as set forth at pp. 3 ¶7 in the previous Office Action (19 July 2004) is hereby *withdrawn* in view of Applicant's amendments (14 December 2004).

3. The Rejection of claim **2** under 35 U.S.C. §112 ¶2 as set forth at pp. 3-5 ¶8-13 in the previous Office Action (17 January 2004) is *withdrawn* in view of Applicant's amendments (14 December 2004).

Maintained Objections And/Or Rejections

4. Claims **1** and **6-9** are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0119518 Stefan *et al.*

5. Applicant traversed the rejection of the claims on the following grounds: **(a)** the instantly claimed nucleic acids of SEQ ID NO: 1 and SEQ ID NO: 3 are not identical to those taught by US 2002/0119518.

6. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

7. On "**(a)**", US 2002/0119518 teaches a nucleic acid sequence (SEQ ID NO: 1; 2782 bp; **[0028]-[0035]**) which has 99.8% sequence homology to the instantly claimed nucleic acid of SEQ ID NO: 1. This sequence encodes an amino acid sequence (SEQ ID NO: 2; 921 aa) which has 100% sequence homology to the amino acid of SEQ ID NO: 2 which is encoded by instantly claimed SEQ ID NO: 1.

8. US 2002/0119518 teaches a nucleic acid sequence (SEQ ID NO: 1; 2782 bp; **[0028]-[0035]**) which has 95.7% sequence homology to the instantly claimed nucleic acid of SEQ ID NO: 3. This sequence encodes an amino acid sequence (SEQ ID NO: 2; 921 aa) which has 100% sequence homology to the amino acid of SEQ ID NO: 4 which is encoded by instantly claimed SEQ ID NO: 3.

9. Therefore the nucleic acid sequence as taught by US 2002/0119518 is within the realm of sequence errors. Furthermore the nucleic acid sequences as taught by US 2002/0119518 are within the realm of the redundancy of the genetic code as they encode for identical amino acids to instantly claimed SEQ ID NO: 1 and 3.

10. In addition, US 2002/0119518 also teaches nucleic acid sequences which are allelic variants, orthologs, paralogs, and mutations including but not limited to substitutions, deletions, inversions, and insertions (**[0149]-[0165]**). US 2002/0119518 teaches that the nucleic acids therein encode sodium/calcium exchangers which are the same as instantly claimed.

11. US 2002/0119518 also teaches vectors and host cells transformed with the above sequences thus meeting the limitations of claims 5-8 (**[0217]-[0249]**).

12. Therefore, since US 2002/0119518 claims the same type of protein (sodium/calcium exchangers) encoded by a nucleic acid nearly identical to the instantly claimed which encodes identical proteins, it is taken by the Examiner to be patentably indistinct.

13. Claims **1** and **6-9** are rejected under 35 U.S.C. 102(e) as being anticipated by WO 02/046415 Lee *et al.*

14. Applicant traversed the rejection of the claims on the following grounds: **(a)** the instantly claimed nucleic acids of SEQ ID NO: 1 and SEQ ID NO: 3 are not identical to those taught by WO 02/046415.

15. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

16. On "**(a)**", WO 02/046415 teaches a nucleic acid sequence (SEQ ID NO: 41; 2966 bp) which has 99.9% sequence homology to the instantly claimed nucleic acid of SEQ ID NO: 1. The nucleic acid sequence of WO 02/046415 differs by a single bp change of T to C at position 1053 but does not changed the protein encoded as the amino acid sequence still has 100% sequence homology to the amino acid of SEQ ID NO: 2 which is encoded by instantly claimed SEQ ID NO: 1.

17. WO 02/046415 also teaches a nucleic acid sequence (SEQ ID NO: 41) which has 95.7% sequence homology to the instantly claimed nucleic acid of SEQ ID NO: 3. This sequence encodes an amino acid sequence (SEQ ID NO: 9; 921 aa) which has 100% sequence homology to the amino acid of SEQ ID NO: 4 which is encoded by instantly claimed SEQ ID NO: 3.

18. Therefore the nucleic acid sequence as taught by WO 02/046415 is within the realm of sequence errors. Furthermore the nucleic acid sequences as taught by WO 02/046415 are within the realm of the redundancy of the genetic code as they encode for identical amino acids to instantly claimed SEQ ID NO: 1 and 3.

19. In addition, WO 02/046415 also teaches nucleic acid sequences which are allelic variants and mutations including but not limited to substitutions, deletions, inversions, and insertions (pp. 21 lines 10-16). WO 02/046415 teaches that the nucleic acids therein encode sodium/calcium exchangers which are the same as instantly claimed (pp. 6-7). Also WO 02/046415 teaches the conservative amino acid substitutions made be made such that the nucleic acid encodes the same protein (pp. 24 lines 15-35) as well as sequence variants which encompass the instantly claimed nucleic acids of SEQ ID NO: 1 and 3 (pp. 26-28).

20. WO 02/046415 also teaches vectors and host cells transformed with the above sequences thus meeting the limitations of claims 5-8 (pp. 32; 43-48; 85-87).

21. Therefore, since WO 02/046415 claims the same type of protein (sodium/calcium exchangers) encoded by a nucleic acid nearly identical to the instantly claimed which encodes identical proteins, it is taken by the Examiner to be patentably indistinct.

22. Claims **1** and **6-9** are rejected under 35 U.S.C. 102(e) as being anticipated by WO 02/33086 Merkulov *et al.*

23. Applicant traversed the rejection of the claims on the following grounds: **(a)** the instantly claimed nucleic acids of SEQ ID NO: 1 and SEQ ID NO: 3 are not identical to those taught by WO 02/33086.

24. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

25. On "**(a)**", WO 02/33086 teaches a nucleic acid sequence (claim 4; Figure 1; 2782 bp; pp. 5) which has 99.9% sequence homology to the instantly claimed nucleic acid of SEQ ID NO: 1. The nucleic acid sequence of WO 02/33086 differs by a single bp change of T to C at position 956 but does not changed the protein encoded as the amino acid sequence still has 100% sequence homology to the amino acid of SEQ ID NO: 2 which is encoded by instantly claimed SEQ ID NO: 1.

26. WO 02/046415 also teaches a nucleic acid sequence (Figure 1; 2782 bp; pp. 5) which has 98.4% sequence homology to the instantly claimed nucleic acid of SEQ ID NO: 3. This sequence encodes an amino acid sequence which has 100% sequence homology to the amino acid of SEQ ID NO: 4 which is encoded by instantly claimed SEQ ID NO: 3.

27. Therefore the nucleic acid sequence as taught by WO 02/33086 is within the realm of sequence errors. Furthermore the nucleic acid sequences as taught by WO 02/33086 are within the realm of the redundancy of the genetic code as they encode for identical amino acids to instantly claimed SEQ ID NO: 1 and 3.

28. In addition, WO 02/33086 also teaches nucleic acid sequences which are allelic variants, orthlogues, paralogues, and mutations including but not limited to substitutions, deletions, inversions, and insertions (pp. 33-37). WO 02/33086 teaches that the nucleic acids therein encode sodium/calcium exchangers which are the same as instantly claimed (pp. 5-6). Also WO 02/33086 teaches single nucleotide polymorphisms in the nucleic acid (pp. 37 lines 14-19; Figure

3) as well as sequence variants which encompass the instantly claimed nucleic acids of SEQ ID NO: 1 and 3 (pp. 33-37).

29. WO 02/33086 also teaches vectors and host cells transformed with the above sequences thus meeting the limitations of claims 5-8 (pp. 38).

30. Therefore, since WO 02/33086 claims the same type of protein (sodium/calcium exchangers) encoded by a nucleic acid nearly identical to the instantly claimed which encodes identical proteins, it is taken by the Examiner to be patentably indistinct.

Summary

31. No claims are allowed.

32. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
April 7, 2005

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600